APR 14 2010

**510K Summary**

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR 807-92(c).

1. The submitter of this pre-market notification is:

Teresa Schmidt
Philips Medical Systems
3000 Minuteman Road
Andover, MA 01810
United States

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Fax: 978-685-5624
Email: teresa.schmidt@philips.com

This summary was prepared on December 18, 2009.

2. The name of the subject device is the Philips IntelliVue Clinical Information Portfolio Release E.0.

3. The trade name of the device the Philips IntelliVue Clinical Information Portfolio.

4. The common usual name is Clinical Information Management System.

5. Device Description: As with the predicate device, the proposed IntelliVue Clinical Information Portfolio (ICIP) is a software only product used for charting and data management. The proposed updated device targets functionality needed for critical care, enhances the user experience, and provide necessary updates to meet hospital IT requirements, as is found in the Philips IntelliVue Clinical Information Portfolio device (K992636). Enhancements for the Critical Care market derived from customer feedback will be added to device in order to meet customer requirements for improved usability. The purpose of this submission is to formally document the renaming of the product to the Philips IntelliVue Clinical Information Portfolio (ICIP) as well as to update the 510(k) filing to include updated technologies needed to meet current hospital IT requirements and improve usability for clinicians

6. The Classification names are as follows:

| Device Panel | Classification | ProCode | Description |
|---|---|---|---|
| **General Hospital** | **Not classified** | **LNX** | **Software, transmission and storage, patient data** |
| **Cardiovascular** | **870.2450, II** | **DXJ** | **Display, medical cathode ray tube** |

7. The modified device is substantially equivalent to the previously cleared HP CareVue 9000 Clinical Information System:
K992636 HP CAREVUE 9000 Clinical Information System

8. The major modifications are as follows:
The purpose of this submission is to formally document the renaming of the product to the Philips IntelliVue Clinical Information Portfolio (ICIP) as well as to update the 510(k) filing to include updated technologies needed to meet current hospital IT requirements and improve usability for clinicians.

9. Comparison with predicate:

| | |
|---|---|
| Predicate Device : | The predicate device is the HP CareVue 9000 Clinical Information System (K992636). |
| Similarities: | The predicate device and the subject device are similar with respect to the intended use and indications for use and fundamental scientific technology:<br><br>*Intended for use in the data collection, storage, and management with independent bedside devices, and ancillary systems that are connected either directly or through networks. This device is indicated for use by health care providers whenever there is a need for generation of a patient record and computation of drug dosage.*<br><br>Additionally, ICIP Release E.0 contains all the main functionality of the predicate. |
| Differences: | There were enhancements to several of the core features such as report enhancements and simple configuration changes. There is a new user interface designed around more modern technologies, this makes the product more user friendly for clinicians, support and scalability. |
| Conclusion: | In conclusion, there are no changes to the intended use or in the fundamental scientific technology employed between the predicate device and the subject devices. Thus, in our opinion, given the substantial equivalence to the predicate devices, no new issues of safety or effectiveness are raised by this premarket notification. |

10. The subject device has the same fundamental technological characteristics as the legally marketed predicate device.

11. Non-Clinical Testing: Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the subject devices with respect to the predicates. Testing involved system level tests, performance tests, and

safety testing from hazard analysis. Pass/Fail criteria were based on the specifications cleared for the predicate device, the specifications of the subject device and test results showed substantial equivalence.

12. Conclusions from Non-Clinical Testing: The results demonstrate that the Philips IntelliVue Clinical Information Portfolio Release E.0 meets all reliability requirements and performance claims and supports a determination of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

APR 1 4 2010

Philips Medical Systems
c/o Ms. Teresa Schmidt
Quality Assurance & Regulatory Engineer
3000 Minuteman Rd
Andover, MA 01810-1099

Re: K100272
Trade/Device Name: Intellivue Clinical Information Portfolio
Regulation Number: 21 CFR 870.2450
Regulation Name: Medical Cathode-Ray Tube Display
Regulatory Class: Class II (two)
Product Code: DXJ, NSX
Dated: March 12, 2010
Received: March 15, 2010

Dear Ms. Schmidt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

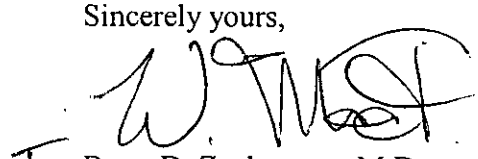
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

**510 (k) Number (if known):** K100272

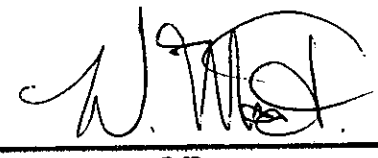
**Device Name:** IntelliVue Clinical Information Portfolio Release E.0

*Intended for use in the data collection, storage, and management with independent bedside devices, and ancillary systems that are connected either directly or through networks. This device is indicated for use by health care providers whenever there is a need for generation of a patient record and computation of drug dosage.*

Prescription Use: YES AND/OR over-the-counter Use: NO
(Part 21 CFFR 801 Subpart D) (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K100272

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